JUN 29 2007

K071488

510(k) Summary

General Information

Classification	Class II
Trade Name	RealHand™ High Dexterity (HD) Instruments.
Submitter	Novare Surgical Systems, Inc. 10440 Bubb Road Suite A Cupertino, CA 95014 Tel: 408-873-3161
Contact	Kerry Pope President & CEO

Intended Use

The RealHand™ High Dexterity (HD) Instruments are intended for grasping, mobilization, dissection, transection and / or suturing of tissue under direct and endoscopic visualization.

Predicate Devices

K043541	Endolink™ True Movement System™ Novare Surgical Systems, Inc.

Device Description

The RealHand Instruments are single use, sterile instruments that consist of a handle, jaws, and a shaft which includes distal and proximal articulating sections. The instruments are similar in size to other instruments and are designed for use through an incision or appropriately sized surgical trocars/ports. The instrument jaws (or scissor blades) are activated by compressing and releasing the handle. The handle can include a ratchet and ratchet release which allow the instrument jaws to be locked in place, a rotation control wheel and articulation lock.

Materials

All materials used in the manufacture of the RealHand Instruments are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included grasping, manipulating, cutting and suturing of tissue.

Testing comparing the RealHand Instruments to a commercially available predicate product was conducted. The products were used per their respective Instructions for Use. The results showed the RealHand Instruments were equivalent to the predicate device.

Summary of Substantial Equivalence

The RealHand Instruments are equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Novare Surgical Systems
% Regulatory Strategies, Inc.
Mr. Gregory Mathison
President
3924 Cascade Beach Road
Lutsen, Minnesota 55612

Re: K071488
Trade/Device Name: RealHand™ High Dexterity (HD) Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 24, 2007
Received: May 30, 2007

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anastacia M Bibb

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application

Device Name: RealHand™ High Dexterity (HD) Instruments

Indications for Use: The RealHand™ High Dexterity (HD) Instruments are intended for grasping, mobilization, dissection, transection and / or suturing of tissue under direct and endoscopic visualization.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X
Prescription Use ___ (Per 21 CFR 801.109)

OR

Over-The-Counter Use (Optional Format 1-2-96)

Anastacia M Bilek

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071488